From: Hangley, William T.
To: "Carolyn Sampson"
Cc: Ferrari, Kim T
Subject: RE: Summary of the American Thalidomide Experience [IWOV-HASP1.FID104272]
Date: Wednesday, February 26, 2020 9:46:50 AM

Ms. Sampson: Because you email of February 2, 2020 addresses substantive matters (as distinguished from, *e.g.*, scheduling matters), I am arranging to place the email and attachment, along with this email, in the public docket.

From: Carolyn Sampson [redacted]
Sent: Sunday, February 2, 2020 11:12 AM
To: Hangley, William T. <wth@hangley.com>; Ferrari, Kim T <kjt@hangley.com>
Subject: Summary of the American Thalidomide Experience

Good morning, Mr. Hangley,

As I wait for more information about my testimony against Kay Reeves and Hagens Berman, I continue to review news articles about thalidomide published in the United States from 1961 through the present.

I'm attaching one that summarizes every bit of information available to the public, published in 1973. The FDA records reveal that they knew but could not prove how many more people might have been affected and this article supports that belief. Perhaps you can attach this as another exhibit in my complaint.

Please note that Merrell has admitted settling claims for 13 Americans. The FDA counted only nine who received samples from Merrell plus eight whose mothers said they got the drug from other countries. This article details some of the barriers to our parents initiating a lawsuit against Merrell on our behalf.

Carolyn Sampson

[redacted]

Thalidomide: the American experience

By Veronica Geng

[The Merrell company's] plans called for marketing thalidomide before . . . spring [of 1961]; estimates are that if they had been successful in their hope, about 10,000 American babies would have been born with gross deformities. That Merrell was not successful is due largely to luck.—James S. Turner, project director, in "The Chemical Feast," The Ralph Nader Study Group Report on the Food and Drug Administration.

Richardson-Merrell, Inc., a New York-based drug company, had high expectations after concluding its 1958 agreement with West Germany's Chemie Grünenthal, licensing Merrell's Cincinnati division to make thalidomide in the United States under the brand name Kevadon. Among drugs that induce sleep or relaxation, the development of thalidomide seemed to have been a breakthrough, largely because it was "suicide-proof." (One man was reported to have swallowed 140 pills, slept for several days, and awaked with merely a bad hangover.) The drug was popular in Germany, and sold over the counter (without prescription) as a sleeping tablet, sedative and tranquilizer—for both adults and, in liquid form, for children. (An American pediatrician called it "West Germany's baby sitter.")

Merrell put thalidomide through some animal studies to supplement what it believed was the "basic research" already done in Germany. In 1959, Merrell started sending thalidomide to doctors for tests on humans. Back then, the F.D.A. had no control over such distribution (and did not get any until 1963). Federal law required only that the company keep its own record of shipments and label them "CAUTION: New drug limited by Federal law to investigational use." Each doctor had to sign a statement that he was a "bona fide clinical investigator"; he did not have to tell patients the drug was experimental. Merrell shipped about 2.5 million thalidomide pills to more than a thousand American doctors, who gave some of the pills to about 20,000 patients, including many women of childbearing age.

In September, 1960, Merrell sent the F.D.A. a New Drug Application, filing its test data and asking permission to market the drug. The application was assigned for review to a newly appointed medical officer, Dr. Frances O. Kelsey, a physician and pharmacologist who is now chief of the scientific investigational staff. She had recently been talking about drug control with her predecessor, Dr. Barbara Moulton, who had resigned in protest over lax F.D.A. policies. As the Nader report said, because of "her conversations, her newness on the job and her dedication, Dr. Kelsey subjected the Merrell application to a standard of review higher than customary." Her suspicions were confirmed, in November, 1961, by German reports linking thalidomide to birth defects. Next summer, Dr. Kelsey received the President's Award for Distinguished Service, the highest Federal

The New York Times
Published: April 29, 1973

civilian honor, and was thanked by President Kennedy for sparing the nation "a human tragedy." (Thalidomide was never returned to the test market or approved for sale. However, it is still in use, under F.D.A.-approved conditions, at the United States Public Health Service's Leprosy Hospital in Carville, La., because it relieves some complications of leprosy. Merrell makes the thalidomide used there.)

In 1962, United States hospitals began reporting births of "thalidomide babies." Since then, 13 claims have been brought against Merrell on behalf of American children. (Some others involve Canadians who say they got the drug through Merrell's Canadian subsidiary.) But right now, no one can be sure about the total number of thalidomide children in this country. (For example, the New York State Health Department began to record reports of birth defects in 1962, when the thalidomide story broke. Dr. Dwight T. Janerich, director of epidemiology and population genetics at the State Birth Defects Institute, says, "There is some evidence that an 'excess' of limb deformations took place in the state in 1962, but further investigation would be needed before any of them could be attributed to thalidomide.")

Michael Dan, a lawyer whose Los Angeles firm represents British children as well as an American 11-year-old, Peggy McCarrick, says that "some families may just not know what's wrong with the child, or that they've got a lawsuit." (Mrs. McCarrick, for instance, was in her teens when she became pregnant, and did not suspect that her baby's malformations were due to thalidomide until she took Peggy to a hospital for medical help.) The time and expense of a law suit that could drag on for five or more years may have discouraged some families altogether. (One family, in Maryland, is waiting to see the outcome of two other cases before deciding what to do.)

The American families have not banded together like those in England because they do not all know of each other's existence. Merrell has refused to disclose some of the names of claimants, and so even the lawyers who represent thalidomide-afflicted children have trouble locating other cases and sharing information.

Of the 13 United States claims, one is still pending in Denver; one, the McCarrick case, was won in Los Angeles in 1971 but is now being appealed by the drug company; one is in negotiation (Merrell refuses to say where); and, since 1968, 10 have been settled out of court (at least five of them in Cincinnati and Philadelphia). It has been Merrell's custom to ask, as a condition of settlement, that the trial records be sealed and impounded by the court; so, although the damages sought in each case have been in the neighborhood of $2-million, the amounts finally awarded remain a secret from the public and from the lawyers and families involved in other cases.

The company emphasizes that since these cases were settled out of court before they went to a jury for a verdict, they do not prove the company was negligent. But the McCarrick case is different: It is the only one that has gone to a jury. In June, 1971, the jury decided for Peggy and her mother, and awarded them $2.5-million in damages ($300,000 more than the McCarricks had asked for). The judge later reduced the damages to $775,000 (because a jury may not award more than the amount asked, and because the judge considered the bonus "excessive.")

Merrell is now appealing the decision, and that case will probably be heard next fall. Whether or not the 1971 verdict is overturned, says Mr. Dan, "the important thing is, we went to a jury and we proved negligence." That victory may prove to be a very useful signpost for lawyers, even if Peggy McCarrick and her mother never get a penny.

The New York Times
Published: April 29, 1973

Dr. Frances O. Kelsey testifying before a Senate subcommittee in August, 1962.

The New York Times
Published: April 29, 1973